K133578

SECTION 5: 510(k) SUMMARY

APR 10 2014

Submitter:
Stryker Sustainability Solutions
1810 W. Drake Drive
Tempe, Arizona 85283

Contact:
Jill M. Clark
Senior Regulatory Affairs Specialist
(480) 763-5300 (o)
(480) 763-5310 (f)
jill.clark@stryker.com

Ramona Kulik
Staff Specialist Regulatory Affairs
480-763-5300 (o)
480-763-2952 (f)
ramona.kulik@stryker.com

Date of Preparation: November 19, 2013

Name of Device:

Trade/Proprietary Name: Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider

Common Name: Bipolar Electrosurgical Open and Laparoscopic Instruments

Classification Name: Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed (21 CFR§878.4400, Product Code NUJ, Class II)

Predicate Device:

Model Number	510(k) Number	510(k) Title	Original Manufacturer
LF1537	K092879	LigaSure 5mm Blunt Tip Laparoscopic Sealer-Divider	Valleylab (currently known as Covidien)

Device Description:

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is a multifunctional electrosurgical instrument for use in performing laparoscopic surgical procedures using the ForceTriad™ Energy Platform.

The outer diameter of the instrument shaft is 5 mm, with a working length of 37 cm. The following controls are located on the instrument handle:

- A lever for opening and closing the instrument jaws. The mechanism incorporates a latch to hold the jaws in the closed position during vessel sealing and cutting.
- An activation button for generator power to initiate vessel sealing.
- A trigger for actuating the cutter. The cutter can only be actuated when the jaws are closed and latched.
- A knob to rotate the instrument jaws.

All controls can be operated with either the right or left hand. Vessel sealing can be initiated using the activation button or utilizing a footswitch connected to the generator.

The instrument attaches to the generator via a ten-foot cable with a Smart™ connector that identifies the instrument type to the generator. The instrument is supplied sterile for single use.

The scope of this submission only includes the reprocessed Covidien™ sealer/divider device and not the ForceTriad™ Energy Platform. Stryker Sustainability Solutions does not reprocess or market the generator.

Intended Use:

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is a bipolar electrosurgical instrument intended for use with the ForceTriad Energy Platform in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider can be used on vessels and lymphatics up to and including 7mm and tissue bundles as large as will fit in the jaws of the instrument.

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and size are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Dividers includes removal of adherent visible soil and decontamination. Each individual device is

tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Dividers. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Tests
- Packaging Validation

Performance testing demonstrates that reprocessed devices perform as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is at least as safe and effective to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

Stryker Sustainability Solutions
Ms. Jill Clark
Senior Regulatory Affairs Specialist
1810 West Drake Drive
Tempe, Arizona 85283

Re: K133578
Trade/Device Name: Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NUJ
Dated: March 10, 2014
Received: March 11, 2014

Dear Ms. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133578

Device Name: Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider

Indications For Use: The Reprocessed LigaSure™ Blunt Tip Laparoscopic Sealer/Divider is a bipolar electrosurgical instrument intended for use with the ForceTriad™ Energy Platform in general and gynecologic laparoscopic surgical procedures where ligation and division of vessels and lymph is desired. The instrument creates a seal by application of RF electrosurgical energy to vascular structures (vessels and lymph) interposed between the jaws of the instrument. A blade within the instrument is surgeon actuated to divide tissue.

Indications for use include general laparoscopic procedures including urologic, vascular, thoracic and thoracoscopic, and gynecologic procedures where ligation and division of vessels is performed. These procedures include: laparoscopically assisted vaginal hysterectomy, Nissen fundoplication, colectomy, adhesiolysis, oophorectomy, etc. The device has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S